

REMARKS

Status of claims:

Claims 15-25 are presented in this RCE Response. Claims 23-25 have been amended.

Amendments:

Amendments to the specification and drawings are submitted herein – correcting errors noted in the respective sections of the application. No new matter has been introduced by virtue of these amendments. Missing Figure 6 is clearly identified in the specification as filed. The drawing simply provides visual correlation to the text description as filed.

Claim Rejections - 35 U.S.C. § 103

Claims 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller, US 5,129,824 (824) taken with Hill, US 5,993,784 (784) and Hill et al., US 5,057,309 (309) in view of Kim et al., US, 6,045,800 (800). The Applicant respectfully traverses this rejection.

In a previous office action, the Examiner stated that Keller teaches a method to treat periodontal disease where the patient can easily administer medication to the infected site by physically removing biofilms from the subgingival, supragingival and interproximal tooth surfaces on a daily basis with brushing, flossing or with an interdental brush (proxy brush).

The Keller '824 patent teaches a method of treating periodontal disease which entails the application of a medicament directly to the infected site. Specifically, the purpose of '824 is to disclose a "method of treatment, which a patient can self-administer, that will cause the bony structure supporting the teeth to regenerate" (col. 2, lines 32-33). The medicaments are antimicrobial or antibiotic in nature, and preferred antibiotics include tetracycline (col. 3, lines 20-23). The claims are directed towards "delivering a medicament to the bony structure of teeth affected by periodontal disease using a delivery device. . . so as to cause the medicament to at least partially bond with said bony structure . . . resulting in a net regeneration of the bony structure of teeth" (col 9-10, lines 28-30 and 1-5). Thus, '824 is directed toward a *chemical* treatment for *bone* regeneration using an *antimicrobial medicament*. The medicament *bonds* with the tooth structure so as to aid in bone regeneration. '824 is also a treatment that requires long contact time in order to achieve optimum results. "Tetracycline appears to bond with the bony structure in the infected areas so as to remain active even between treatments" (col. 7, lines 16-18). The authors recommend a regular regimen to insure "that the benefits of the tetracycline medicament are continuous" (col. 7, lines 30-31).

In contrast, the claimed invention is drawn towards a three-step, self-administered, *soft-tissue* management program. The claimed invention is primarily a *physically abrasive* method for treating the subgingival, supragingival and interproximal areas of tooth surfaces for periodontal patients with gingival detachment of about 3 mm and greater. The teaching of '824 is chemical in nature (antimicrobial) and targeted towards bonding with the tooth surface and promoting regeneration of the *bone structure* of the tooth itself. No abrasives or abrasive methods are mentioned in '824, and the only other substances listed as possible ingredients to include with the tetracycline are other medicaments such as fluoride and other antimicrobials such as hydrogen peroxide (col. 7, lines 1-15). In contrast, the soft abrasives used in the claimed invention are *inert* substances that work by physically disrupting biofilms. Furthermore, '824 requires long

contact times in order for the medicament to obtain maximum impact and treatment timing is scaled depending on the advancement of the periodontal disease. “Preferably, the medicament should be applied every 8-12 hours at the start of the treatment, then later in the treatment twice a day, and finally 3-4 times a week in a maintenance program” (col. 7, lines 27-29). In contrast, the current invention does not require long contact times (since it works via an abrasive method on tissue, and not chemically on bone), and emphasis is placed on a quick, easy treatment that can be done several times a day. One of the suggested methods for treatment in ‘824 includes a form fitted flexible tray assembly that actually conforms to the patients’ teeth. This method implies that the tray assembly needs to stay in the patient’s mouth for at least some amount of extended time, (Example 5 shows the patient wearing the tray overnight) and thus further reinforces the fact that ‘824 is not a quick method of treatment.

Furthermore, ‘824 includes a treatment method using a syringe, which is certainly not as easy to use or as safe as the methods described in the claimed invention. Also, the interdental toothbrush in ‘824 is hollow in structure so that medicament is housed within and when ready to use, a seal is removed from the tip of the interdental brush. The hollow structure is squeezed and the medicament travels through a channel from the hollow structure onto the brush head. The use of the seal and the pre-loaded medicament imply that the device is limited in its number of uses. No such limitation is present in the claimed invention and the ribbed and grooved bristles of the claimed proxy brush allow more soft abrasives to be delivered to the biofilm than regularly shaped round bristles. Table 1 and Graph 1 clearly show the superior performance of the ribbed and grooved bristle shape over that of the conventional round shape. ‘824 makes no mention of using bristles of a ribbed and grooved shape.

The Hill ‘784 patent discloses a method of treatment which comprises brushing with a low foam toothpaste containing: a therapeutic substance, an abrasive, a humectant,

a low foam surfactant, and/or a foam control agent. The claims are drawn to include specific compositions of the toothpaste and include a method of treating the oral cavity by brushing with the toothpaste. '784 states "during toothbrushing, the primary function of the toothbrush bristles is to rub abrasive particles contained in the toothpaste across the surfaces of the teeth" (col. 1, lines 57-59). The abrasives in '784 have particle sizes of 3 and 25 microns and are preferably between 6 and 20 microns (col. 7, lines 25-27). '784 is directed toward a method of cleansing that optimizes abrasive cleaning techniques using a channeled bristle toothbrush to entrap the abrasive contained in the toothpaste. The low-foaming property in the toothpaste is desired so as not to interfere with the abrasive-entrapment property of the toothbrush (col. 2-3, lines 66-67 and 1-4).

It is well known in the art that the combination of brushing with a toothbrush and toothpaste alone cannot reach the interproximal spaces or the subgingival surfaces of the tooth. Toothbrushing is capable of attacking only the supragingival plaque containing areas of the tooth surface. Thus, the whole thrust of '784 is restricted to cleaning only the outer surfaces of the tooth with an enhanced abrasive technique, and therefore does not address cleaning the interproximal surfaces. In an earlier Office Action, the Examiner contended that '784 taught administering soft abrasives into subgingival-deepened gingival sulcus. The Applicant respectfully disagrees. '784 states "the development of gingival inflammation and dental caries is most frequently caused by failure to remove dental plaque from the subgingival surface of the tooth and to a much lesser extent material alba from the gingival surface in the subgingival space" (col. 2, lines 4-8). '784 suggests a *need* to remove plaque from the subgingival surfaces but fails to provide or suggest a means for doing so. Furthermore, the soft abrasives in the present invention can have a wide variety of sizes, including sizes of 30-60 microns (examples 2 and 6), which is clearly outside the preferred range of 6-20 microns in '784. Based on these comments, '784 discloses an abrasive technique that is restricted to the outer surface of the tooth and fails to address treating the subgingival and interproximal areas of the tooth

surface with dental floss, dental tape or proxy gels containing soft abrasives such as those in the claimed invention.

The Hill '309 patent describes an ingestible, non-foaming, non-aqueous liquid and semi-solid oral hygiene preparation. The preparation contains a microbially active form of stannous fluoride. The authors stress that "the effective use of SnF_2 has been drastically limited by its inherent instability in the presence of oxygen, water, abrasives, etc." (col. 1, lines 50-53). Abrasive-free is defined as "containing no abrasive, nor abrasive-like substance normally used in dentifrices, or containing trace amounts of these substances such that their characteristic abrasive action cannot be perceived nor their adverse effect on microbially active SnF_2 established" (col. 4, lines 6-12). '309 is thus an oral treatment that is *chemical* (antimicrobial) in nature, *aqueous-free* and contains *no abrasives*. In fact, the functionality of '309 would be destroyed in the presence of abrasives and water.

In contrast, the claimed invention teaches an abrasive technique that uses soft abrasives in a composition containing water. Both Examples 27 (soft abrasive containing proxy gel) and Example 28 (soft abrasive toothpaste) list water as an individual component in the formulation. Given the chemical treatment method cited in '309, and the fact that the main method of treatment in the claimed invention is abrasive and aqueous in nature, one skilled in the art would not be motivated to combine components of the coating in '309 with the coating of the claimed invention since the aqueous and abrasives ingredients destroy the effectiveness of the '309 coating. Furthermore, since the treatment method in '309 is topical in nature, it does not teach or suggest treatment to the subgingival or interproximal surfaces of the tooth. The examples and embodiments disclosed in '309 are drawn to sprays, rinses, creams, gels and pastes, all of which are meant to remain on the surfaces of the oral cavity and work with "a minimum of mechanical action and without foaming" (col. 7, lines 38-40).

The '800 patent teaches the use of a specific extract of *Achyranthis radix* or *Ulmus cortex* as providing the desired effect of inhibiting the production of the periodontal disease-inducing agents and at the same time inhibiting the activity of the periodontal tissue-decomposing enzyme for periodontal tissues, as well as promoting collagen synthesis. The active agents are extracts from medicinal herbs and this treatment is *biochemical* in nature. Furthermore, like '784 and '309, '800 is topical in nature (see examples 1-6 and 2-6) and thus supragingival in its treatment method. '800 fails to mention or suggest treating the subgingival and interproximal areas of the tooth surface.

In a previous office action, the Examiner stated that the '800 patent taught the subject matter of claims 23-25, which are directed to adding an anti-inflammatory agent to the dentifrices, and (from '800) these therapeutic substance could be chlorhexidine gluconate, cetylpyridium chloride, and triclosan. Given the current amendments made to claims 23-25, this rejection is now moot. However, the Applicant respectfully disagrees with the Examiner's contention that chlorhexidine gluconate, cetylpyridium chloride, and triclosan are members of the anti-inflammatory family and respectfully point out that these substances are actually part of the anti-bacterial family. Furthermore, claims 23-25 of the claimed invention mention a therapeutic agent that can be used *in addition* to the abrasive method of removing biofilms.

Each claim in the claimed invention must be read as a whole when being analyzed for obviousness. Combining the teachings of '824, '784, '309 and '800 does not yield the three-step abrasive method and treatment cited in the claims. The '824 patent teaches a method for regenerating bone structure via a chemical means that requires long residency times and since the abrasive technique in the '784 patent does not regenerate bone structure it doesn't make sense to combine them. Furthermore, the chemical treatment method of '309 does not support compositions containing water or abrasives and thus

would not work in combination with the abrasive composition of the '784 patent. The '800 patent is also a chemical treatment and lists secondary anti-bacterial ingredients and makes no mention of anti-inflammatory agents.

Applicant submits that due to the differences between the teachings of the proposed combination of the cited prior art and the presently claimed method, the art, when considered as a whole, fails to make the presently claimed method obvious. Thus, the Section 103 rejection should be reconsidered and such action is respectfully requested by the Applicant.

EXTENSION OF TIME

Applicant hereby petitions for a two-month extension of time in connection with the filing of this response. The initial three-month response deadline expired on October 9, 2008.

FEE AUTHORIZATION

Please charge all fees due in connection with this filing to Deposit Account No. 19-0733.

Respectfully submitted,
/Ernest V. Linek/
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